

administered or dispensed. Additional persons who are qualified persons pursuant to section 319F-3(i)(8)(B) are the following: None.

#### VII. Additional Time Periods of Coverage After Expiration of Declaration (as Required by Section 319F-3(b)(3)(B) of the Act)

A. I have determined that, upon expiration of the applicable time period specified in Section III above, an additional twelve (12) months is a reasonable period to allow for the manufacturer to arrange for disposition of the Covered Countermeasure, including the return of such product to the manufacturer, and for covered persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasure, and the liability protection of section 319F-3(a) of the Act shall extend for that period.

B. The Federal Government shall purchase the entire production of Covered Countermeasures under the contracts specifically listed by contract number in section I for the stockpile under section 319F-2 of the Act, and shall be subject to the time-period extension of section 319F-3(b)(3)(C). Production under future contracts for the same vaccine will also be subject to the time-period extension of section 319F-3(b)(3)(C).

#### VIII. Amendments

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 vaccines was published on January 26, 2007 and amended on November 30, 2007 to add H7 and H9 vaccines and on October 17, 2008 to add H2 and H6 vaccines. This Declaration incorporates all amendments prior to the date of its publication in the **Federal Register**. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F-2(b)(4) of the Act.

#### IX. Definitions

For the purposes of this declaration, “pre-pandemic phase” means the following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas. For the purposes of this declaration, “pandemic phase” means the following stages, as defined in the

National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (4) First Human Case in North America; and (5) Spread Throughout United States.

Dated: June 15, 2009.

**Kathleen Sebelius,**  
Secretary.

#### Appendix

##### I. List of U.S. Government Contracts—Covered H5N1 Vaccine Contracts [January 26, 2007]

1. HHSN266200400031C
2. HHSN266200400032C
3. HHSN266200300039C
4. HHSN266200400045C
5. HHSN266200205459C
6. HHSN266200205460C
7. HHSN266200205461C
8. HHSN266200205462C
9. HHSN266200205463C
10. HHSN266200205464C
11. HHSN266200205465C
12. HHSN266199905357C
13. HHSN266200300068C
14. HHSN266200005413C
15. HHSO100200600021C (formerly 200200409981)
16. HHSO100200500004C
17. HHSO100200500005I
18. HHSO100200700026I
19. HHSO100200700027I
20. HHSO100200700028I
21. HHSO100200600010C
22. HHSO100200600011C
23. HHSO100200600012C
24. HHSO100200600013C
25. HHSO100200600014C
26. HHSO100200600022C (formerly 200200511758)
27. HHSO100200600023C (formerly 200200410431)
28. CRADA No. AI-0155 NIAID/MedImmune
29. HHSO100200700029C
30. HHSO100200700030C
31. HHSO100200700031C

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

[60 Day-09-09BX]

##### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects.

Alternatively, to obtain a copy of the data collection plans and instrument, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, NE., MS-D74, Atlanta, Georgia 30333; comments may also be sent by e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of information technology. Written comments should be received within 60 days of this notice.

#### Proposed Project

*Clostridium difficile* Infection (CDI) Surveillance—New—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Steady increases in the rate and severity of *Clostridium difficile* infection (CDI) indicate a clear need to conduct longitudinal assessments of the impact of CDI in the United States. *C. difficile* is an anaerobic, spore-forming, gram positive bacillus that produces two pathogenic toxins: A and B. CDI ranges in severity from mild diarrhea to fulminant colitis and death. Transmission of *C. difficile* occurs primarily in healthcare facilities, where environmental contamination by *C. difficile* spores and exposure to antimicrobial drugs are common. No longer limited to healthcare environments, community-associated CDI is the focus of increasing attention. Recently, several cases of serious CDI have been reported in what have been considered low-risk populations, including healthy persons living in the community and peri-partum women.

For this proposed data collection, the surveillance population will consist of persons residing in the catchment area of the participating Emerging Infections Program (EIP) sites. This surveillance poses no more than minimal risk to the study participants as there will be no interventions or modifications to the care study participants receive. EIP surveillance personnel will perform active case finding from laboratory reports of stool specimens testing